



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/155,252	09/21/1998	RONALD MARK EVANS	SALK1470-2	8370

7590 08/22/2002  
STEPHEN E REITER  
FOLEY & LARDNER  
P O BOX 80278  
SAN DIEGO, CA 92138-0278

EXAMINER

BUNNER, BRIDGET E

ART UNIT	PAPER NUMBER
----------	--------------

1647

DATE MAILED: 08/22/2002

24

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/155,252

Applicant(s)

EVANS ET AL.

Examiner

Bridget E. Bunner

Art Unit

1647

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED <sup>7/26/02</sup> FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_

3. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_

Claim(s) objected to: \_\_\_\_\_

Claim(s) rejected: 16-20, 27 and 28.

Claim(s) withdrawn from consideration: \_\_\_\_\_

8. ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
10. ☐ Other: \_\_\_\_\_

Continuation of 3. Applicant's reply has overcome the following rejection(s): the rejection of claims 16-20 and 27-28 under 35 U.S.C. §112, second paragraph.

Continuation of 5. does NOT place the application in-condition for allowance because: Claims 16-20 and 27-28 are rejected under 35 U.S.C. § 112, first paragraph. Applicant asserts that Example 3 of the specification provides a complete exemplary screening assay for PPAR-gamma-selective agonists. Applicant argues that this assay utilizes cells comprising both a peroxisome proliferator activated receptor-gamma (PPAR-gamma) (introduced by way of a receptor expression construct) and a reporter vector (comprising a promoter, a GAL4 response element and a reporter protein) to test compounds for their ability to regulate PPAR-gamma transcription activation of the reporter vector. Applicant contends that the GAL4 response element is used because the screening assay is performed with a chimeric PPAR-gamma receptor (CMX-GAL-PPAR gamma), which requires the GAL4 response element as its DNA binding site. Applicant indicates that one of skill in the art could make and use a complementary pair of receptor and reporter constructs by following the teachings of the specification. Applicant's arguments have been considered but are not found persuasive for the following reasons. In response to applicant's argument, it is noted that the features upon which applicant relies (i.e., a peroxisome proliferator activated receptor gamma expression construct) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). According to Applicant, one skilled in the art must have a receptor expression construct and a reporter construct expressed in cells in order to practice the claimed invention. Therefore, the specification does not teach the claimed method of contacting a cell that contains a *peroxisome proliferator activated receptor-gamma* and a reporter vector with any compound, agonist, or antagonist. One skilled in the art cannot predict that an increase or decrease in the level of reporter protein will be detected in the claimed assay since the receptor is not chimeric and does not contain a hormone response element binding domain (which is necessary to express the reporter protein).

Proper analysis of the Wands factors was provided in the previous Office Action. Due to the large quantity of experimentation necessary to regulate transcription activation of PPAR-gamma by assaying the levels of a reporter protein wherein the reporter vector comprises a promoter, a hormone response element, and a DNA segment encoding the reporter, the lack of direction/guidance presented in the specification regarding the same, the absence of working examples directed to the incubation of a cell containing PPAR-gamma and a reporter vector with any compound and any agonist or antagonist, the complex nature of the invention, and the unpredictability of detecting an increase or decrease in the level of reporter protein, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention.

*Mary L. King*